

**PHARMACY EXAMINING BOARD
MADISON, WI
MINUTES
JULY 9, 2003**

PRESENT: Cynthia Benning, R.Ph., Michael Bettiga, R.Ph., John Bohlman, R.Ph.;
Georgina Forbes, Dan Luce, R.Ph.; Charlotte Rasmussen, Susan Sutter,
R.Ph.

STAFF PRESENT: Tom Ryan, Bureau Director; William Black, Legal Counsel;
Pamela Meicher, Program Assistant; DOE Staff

GUESTS: Shelley Raebel, Purdue Pharma; Gina Bestemar, Women's International
Pharmacy; Paul Baum, Group Health Cooperative; Tom Engels, Pharmacy
Society of Wisconsin; Rhett Koski, student UW School of Pharmacy;
Jamie Statz Paynter, Dean Pharmacy; Heather Waite, UW Health

CALL TO ORDER

Susan Sutter, Chair, called the meeting to order at 9:02 a.m. A quorum of 7 members was present.

AGENDA

Amendments to agenda:

Page 62 - Application for Pharmacist License was replaced with an updated version.
Proposed legislation relating to the use of federal drug enforcement administration registration numbers and providing a penalty. (D)
Letter from the U.S. Department of Justice Drug Enforcement Administration addressing the requirement for a pharmacy to obtain a new state license pursuant to an address change. (F)
Pending Cases Report
Informational item – Invitation to Write Test Questions

MOTION: Georgina Forbes moved, seconded by Dan Luce, to approve the agenda as amended. Motion carried unanimously.

APPROVAL OF MINUTES OF JUNE 19, 2003

Corrections to minutes:

Page 1 – Correct two guest names; Franklin LaDien and Paul Baum.
Page 2 – Correct the two first motions on page 2 to show that John Bohlman moved both motions.

Page 2 – Add: **MOTION:** Michael Bettiga, seconded by Dan Luce, to resubmit Rule 01-075 relating to central fill, to the legislature with changes. Motion carried unanimously.

Page 3 – Correct the last sentence of the Practice Question – Designation of Dosage Form by a prescriber to “The Board decided that the pharmacists can use their professional judgment for the dosage as long as the drug is consistent and there is no difference in the dosage.”

Page 3 – Correct the first sentence under Temporary Variance Request – Agnesian Healthcare, Inc., Fond du Lac to read “The Board discussed the request from Craig W. Griffis, R.Ph., Director of Pharmacy, Agnesian HealthCare, Inc., requesting a variance to establish a pharmacy at the FDL County Expo Center in the event of a high casualty biological or chemical incident.”

Page 4 – Correct sentence after Variance Request (follow up) – NeighborCare – Menomonie to read “After a brief discussion the Board determined that a letter should be sent to NeighborCare advising it that this request has been tabled. William Black, Legal Counsel, will coordinate with DOE to ensure a letter goes out.”

MOTION: Michael Bettiga, seconded by Dan Luce, to approve the minutes of June 19, 2003 with corrections. Motion carried unanimously.

ADMINISTRATIVE REPORT

Tom Ryan indicated Secretary Strong Hill has requested that Boards begin discussing problems related to health care underservice, including the shortage of pharmacists in Wisconsin. Some suggestions offered in the past to remedy the pharmacist shortage include opening a new pharmacy school in Wisconsin, continuing discussions with the Leadership Summit/Pharmacy Forum group, and to make efforts toward realizing greater impact on the shortage problem from the gains of technological efficiency. The Board also suggested that the state allocate time for staff to attend discussions among pharmacy professionals or conduct reviews of minutes from past discussions.

Tom Ryan asked that if the Board has any agenda items for the September meeting to submit them to Susan Sutter three weeks in advance of the meeting, if possible.

Susan Sutter gave a brief overview of the Board Chair meeting held by Secretary Strong Hill on June 24. Discussion ensued regarding Board spending priorities. Maintaining existing staff is a leading priority, and the need for an enforcement attorney was noted. The Board supports increased use of the Department’s website for the Regulatory Digest and as a reference point for the Board’s rules, and occasional use of postcard mailings was suggested.

AB 355 UPDATE

The Board discussed AB 355. The Board requested the Department provide an analysis of the bill at its next meeting. Specific concerns that were noted include: the discipline required by the bill is not funded, some of its provisions would be administratively cumbersome, reporting

requirements appear difficult to monitor, and there is some confusion of DHFS and DRL roles in administering some of the bill's provisions.

MOTION: Dan Luce moved, seconded by Charlotte Rasmussen, to appoint Susan Sutter as the Board liaison to the legislature on AB 355. Motion carried unanimously.

PROPOSED LEGISLATION RELATING TO USE OF FEDERAL DRUG ENFORCEMENT ADMINISTRATION NUMBERS AND PROVIDING A PENALTY

The Board briefly discussed the proposed legislation on the restrictions on use of federal registration numbers. The DEA has suggested to the Board that a federally assigned number be used rather than the federal registration number, as is currently the practice in Minnesota.

SUMMARY REPORTS ON PENDING COURT CASES, DISCIPLINARY CASES, ADMINISTRATIVE RULES AND LEGISLATION

Tom Ryan will bring back the active list (Rule Status) for the Board to review at its August meeting. The Board will decide which rules are current.

SCOPE STATEMENT – DISCUSSION OF PARTIAL REPEAL – WIS. ADMIN. CODE § PHAR 2.03 (4)

William Black, Legal Counsel, will incorporate the Board's suggestions into a scope statement supporting partial repeal of Wis. Admin. Code § Phar 2.03 (4). The scope statement will be presented to the Board at its August meeting.

MOTION: John Bohlman moved, seconded by Michael Bettiga, in favor of William Black writing a scope statement for the language changes in Wis. Admin. Code § Phar 2.03 (4). Motion carried unanimously.

WIS. ADMIN. CODE § 6.04 (3) – PHARMACIST ABSENCE – REVIEW AND REVISION

Legal Counsel, William Black, provided the Board with proposed language changes to Phar 6.04 (3). After a brief discussion on the changes, the Board decided to send the changes relating to pharmacist absence to the Clearinghouse.

MOTION: John Bohlman moved, seconded by Dan Luce, to send the language changes in Wis. Admin. Code § Phar 6.04 (3) to the Clearinghouse. Motion carried unanimously.

WIS. ADMIN. CODE § 6.02 (2) – PHARMACY CHANGE OF ADDRESS – REVIEW

The Board discussed a letter received from the U.S. Department of Justice Drug Enforcement Administration addressing the requirement of obtaining a new state license pursuant to an address change (Chapter 450.06(3), Wis. Stat.). After discussion, the Board decided it would

support the transfer of a license to a new location in place of the current requirement for new licensure. William Black will draft a scope statement for the proposed change. The Board suggested the rule, when drafted, define location change and specify the criteria that must be considered when a change of location is sought.

MOTION: Georgina Forbes moved, seconded by Dan Luce, that William Black write a scope statement for the language changes in Wis. Admin. Code § Phar 6.02(2). Motion carried unanimously.

CREDENTIALING TRANSITIONS-CATHY POND, DEANNA ZYCHOWSKI

Cathy Pond advised the Board that she meets weekly with Deanna Zychowski about credentialing issues that affect the Department. Ms. Pond said that the Credential Division is identifying licenses that must be presented to the Board. Currently those include violations in other states and certain disciplinary issues of pharmacists or managers, in addition to malpractice, impairment, and active practice pharmacy. Susan Sutter will work with Ms. Pond as the Board contact on the active practice pharmacy form.

REGULATORY DIGEST

Tom Ryan advised the Board that the department is currently reviewing the format, coordination and distribution of the Regulatory Digest. One option under consideration is the creation of an internet based worksite, by profession, available at the Department's website.

DATCP PRESCRIPTION DRUG COUNT VERIFICATION (FOLLOW UP)

William Black, Legal Counsel, will provide an update to the Board at a future meeting if further information is forthcoming.

INSPECTIONS ARTICLE FOR LICENSING PACKET

The Board reviewed a draft of the self inspection form for new pharmacies, which was provided by David O'Connell, Screening Supervisor in the Division of Enforcement. The Board would like the inspection form to be part of the application packets for new pharmacies.

MOTION: John Bohlman moved, seconded by Michael Bettiga, for the inspection draft to be included in the application packet, with changes provided by Chairperson Susan Sutter. Motion carried unanimously.

WISCONSIN STATE JOURNAL TELEPHONE CALL

MOTION: Dan Luce moved, seconded by Michael Bettiga, for Susan Sutter to respond to the Wisconsin State Journal on doctor's handwriting. Motion carried unanimously.

DRL FEE STUDY REPORT

Tom Ryan discussed the DRL Fee Study Report, which was not accepted by the Joint Finance Committee. Mr. Ryan also advised the Board that since the department has cut ten positions, as a result of a previous budget cut, it has been instructed to cut an additional \$290,000 from its budget.

To that end, the department is currently reviewing expenditures. Discussion ensued regarding the fee study and the budget. Elizabeth Reinwald, DRL Budget Director, was present for the discussion. Cost saving options reviewed during a previous Board discussion (see page 2) were considered. Ms Reinwald indicated more Departmental time keeping should be anticipated, as the time spent by all Divisions other than DOE is currently not tracked by profession served. The Board indicated questions remain with respect to the fee methodology. The Board decided it would forward a summary of its spending priorities to the Secretary through Chairperson Sutter.

CENTRAL FILL – WILLIAM DUSSO

William Dusso, the Department's General Counsel, gave an update to the Board on the central fill rule. A new fiscal estimate for the central fill is currently in progress. Secretary Strong Hill has requested that all Board rules be analyzed by the fiscal office prior to legislative review. Mr. Dusso reported that Department policy has been revised to include an estimate of the fiscal impact of a rule with the formatted rule when it is sent to the legislature. An accurate estimate of costs should assist the legislature in its ongoing assessment of agency resource needs. Mr. Dusso further stated that there are currently 8-10 rules in progress for the Pharmacy Examining Board.

USP UPDATE – CINDY BENNING

Cindy Benning advised the Board that under USP re-processing standards, 30-day blister packs can no longer be reused or repacked due to concerns about drug integrity after a seal is breached. The Board is not confident that the impact of the USP reprocessing standards on daily practice is fully understood. William Black will research this issue further and report back to the Board at a future meeting.

COMPLIANCE QUESTION – PHARMERICA – BELTSVILLE, MD

James Kilgus, RPh, Clinical Consulting Director of PharMerica, asked the Board if blanket authorization allowing conversion of a non-formulary medication to a formulary medication within a long term care facility is allowed by statute or regulation. Jurisdictional conflict was noted. William Black will draft a letter advising PharMerica to consult DHFS rules relating to Wis. Stat. § 450.02 (4)(b).

COMPLIANCE QUESTION – WELDON V. ZUFELT – SHEBOYGAN, WI

The letter received from Attorney Zufelt did not specify exactly what role Mr. Zufelt's client plays as a liaison between pharmaceutical manufacturers and customers, but he does state his client never takes possession of the drugs. Michael Bettiga asserted that if Mr. Zufelt's client does not take possession of the drugs, the client is not, by current definition, a distributor, and no license would be required.

COMPLIANCE QUESTION – CALUMET MEDICAL CENTER, CHILTON, WI

William Black led the discussion of Calumet's drug dispensing machine. Per Mr. Black, the machine will be in the Calumet pharmacy and controlled by St. Elizabeth's hospital, but because there is no on-site pharmacist staff and no pharmacist will be assigned to the medical center for a duration that comports with statutory requirements, the dispensing machine should be regulated as a drug room is regulated. Mr. Black will draft a letter for the Board's review advising Calumet Medical Center to ensure it is in compliance with DHFS rules regarding drug rooms. Other options related to remote dispensing may be offered in the letter.

COMPLIANCE QUESTION – AURORA PHARMACY- MARINETTE, WI

William Black will draft a letter to the Aurora Pharmacy advising it that Wisconsin law does not recognize temporary closing of a pharmacy. All licensed pharmacies are expected to be open. As here, the question of closure is often confused with the threshold question of how long a pharmacy may remain in operation, whether dormant or active, without a managing pharmacist.

COMPLIANCE QUESTIONS (2) – SACRED HEART – ST. MARY'S HOSPITALS, INC. – RHINLANDER, WI

After reviewing the pharmacy policy and procedure for Sacred-Heart-Saint Mary's Hospitals, Inc., the Board has requested that William Black draft a letter advising the pharmacy that it must comply with state statutes on labeling and outpatient dispensing. Mr. Black will also caution the pharmacy that prescriptions should be read and filled as a delegated act by a medical doctor.

COMPLIANCE QUESTION – DMSO SALES – WILLIAM E. BASTIAN

William Black will advise William E. Bastian that dimethyl sulfoxide is primarily a veterinary drug. It was noted that the drug has been approved for only one known human use, intestinal cystitis. Mr. Bastian will be referred to the Veterinary Examining Board Legal Counsel for further detail.

COMPLIANCE QUESTION – RE-LABELING DELEGATION – JAMES BUDDE – MADISON, WI

The Board agreed that nurses can re-label prescriptions in a hospital setting but not in a nursing home setting.

**COMPLIANCE QUESTION – DOSAGE FORM FOR SCHEDULE II PRESCRIPTIONS
(REVISITED) – NICOLE TIEMAN, R.PH.**

William Black advised the Board that strength and dosage forms are required by federal law and that controlled substances also require dosage forms. Mr. Black will consult with DEA by letter before responding.

**PHARMACIST RE-REGISTRATION – EXAM REQUIREMENTS – ALLEN SANDVIG,
R.PH. – WIND LAKE, WI**

The Board has requested that Kris Hendrickson advise Allen Sandvig, R.Ph, that he must take the Law and Patient Consultation examination.

REQUEST FOR LICENSURE – COLIN E. BAYLISS – DOVER, OH

The Board took no action on this request because a completed application has not been received by the department.

**PHARMACY APPLICATION – WAL-MART PHARMACY 10-5090 – GREENVILLE,
WI**

MOTION: John Bohlman moved, seconded by Charlotte Rasmussen, to approve the application of Wal-Mart Pharmacy 10-5090. Motion carried unanimously.

ACCEPT EXAM SCORES

MOTION: Michael Bettiga moved, seconded by Dan Luce, to accept all the examination scores as provided by the Examinations Office. Motion carried unanimously.

CLOSED SESSION

MOTION: Charlotte Rasmussen moved, seconded by Michael Bettiga to convene to closed session pursuant to Wisconsin State statutes 19.85 (1) (a) (b) (f) and (g) to deliberate on stipulations, stays, request for modification of screening and supervised hours, administrative warnings, issuance of complaints, review of application, case status report and consulting with legal counsel. Motion carried by roll call vote: Cynthia Benning-yes, Michael Bettiga-yes, John Bohlman-yes, Georgina Forbes-yes, Dan Luce-yes, Charlotte Rasmussen-yes, Susan Sutter-yes.

Open session recessed at 12:41 p.m.

RECONVENE INTO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

MOTION: Charlotte Rasmussen moved, seconded by Michael Bettiga, to reconvene into Open Session at 2:23 p.m. Motion carried unanimously.

VOTING ON ITEMS DELIBERATED OR CONSIDERED IN CLOSED SESSION

REQUEST FOR THREE MONTH STAY

MARK ANDERSON, R.PH.

MOTION: Charlotte Rasmussen moved, seconded by Dan Luce, to grant the request of Mark Anderson, R.Ph., for a 3-month stay and modify his order to change his pharmacist in-charge hours from 16 to 24 hours a week. Motion carried unanimously.

ROBERT GUZZETTA, R.PH.

MOTION: John Bohlman moved, seconded by Charlotte Rasmussen, to grant the request of Robert Guzzetta, R.Ph., for a 3-month stay. Motion carried unanimously.

JOHN LITZENBERG, R.PH.

MOTION: Dan Luce moved, seconded by Charlotte Rasmussen, to grant the request of John Litzenberg, R.Ph., for a 3-month stay, deny his request for modifications to his order and advise him that he can reapply for full licensure at the next Pharmacy Examining Board meeting 08/13/03. Motion carried unanimously.

KEVIN PAMPUCH, R.PH.

MOTION: Michael Bettiga moved, seconded by Charlotte Rasmussen, to grant the request of Kevin Pampuch, R.Ph., for a 3-month stay and to reduce his therapy from once a week to every other week. Dan Luce abstained. Motion carried.

REVIEW CHALLENGE – TARA STRANG

MOTION: Michael Bettiga moved, seconded by Charlotte Rasmussen, to deny the examination challenge of Tara Strang. John Bohlman abstained from the discussion. Motion carried.

INFORMATIONAL ITEMS

Pharmacy examinations will be scheduled at the department on August 12, 2003.

Susan Sutter advised the Board that DOE is sending inspectors to her pharmacy for training next week.

Tom Ryan advised the Board that the 800 number at the department will now be answered by the receptionist.

Michael Bettiga will attend the Green Bay discussion and John Bohlman will attend the La Crosse discussion, Cynthia Benning will attend the Milwaukee discussion and Susan Sutter will attend the Madison and Wausau discussions on pain management. Tom Ryan, Bureau Director abstained from the discussion.

The Board representative will ask other pharmacists at the next Wisconsin Pharmacy Forum meeting if they will suggest volunteers to assist in writing examination questions for the Board.

ADJOURNMENT

MOTION: Charlotte Rasmussen moved, seconded by Cynthia Benning, to adjourn the meeting at 2:55 p.m. Motion carried unanimously.

Next Meeting Wednesday, August 13, 2003